UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 24-CR-20255-WPD

UNITED STATES OF AMERICA

v.

PATRICK BOYD and
CHARLES BOYD,

Defendants.
_____/

UNITED STATES' DISCLOSURE OF LAY WITNESS OPINION TESTIMONY

The United States of America hereby files this Disclosure pursuant to Federal Rule of Evidence 701 regarding lay opinion testimony from fact witnesses. It is the Government's position that none of the testimony offered by certain of the Government's fact witnesses will go beyond lay opinions under Rule 701 and the case law applying it. However, in the exercise of prudence and an abundance of caution, the Government is nonetheless providing this disclosure in the event any aspect of these witnesses' testimony is deemed to contain expert testimony. The witnesses are:

(1) Christina Picard, Regulatory Counsel, Center for Drug Evaluation and Research Office of Compliance/Office of Drug Security, Integrity, and Response, U.S. Food and Drug Administration ("FDA");

(2) Susmitha Sunkara, Senior Director of Quality, Gilead Sciences;

(3) Harpreet Dhanota, Director, Head of Global Investigations Relating to Counterfeiting, Diversion, and Product-related Fraud, Gilead Sciences; and

(4) Christopher Trent, Director, Global Brand Protection, North America, Johnson & Johnson.

1. Christina Picard (FDA)

Ms. Picard had telephone and email interactions with Defendant Charles Boyd and others associated with Safe Chain Solutions LLC ("Safe Chain"). She also has personal knowledge of the FDA Form 3911s (Drug Notification Forms) that were filed on behalf of Safe Chain as well as FDA Form 3911s that were filed by other entities related to Safe Chain's distribution of prescription drugs during the conspiracy period. Ms. Picard will introduce and testify about those forms. Relatedly, Ms. Picard will testify about FDA Form 3911s that were not filed on behalf of Safe Chain. In addition, Ms. Picard will testify about the requirements imposed by the Drug Supply Chain Security Act ("DSCSA") and by the FDA on wholesale distributors of prescription drugs like Safe Chain during the charged conspiracy period, and the purpose of these laws and regulations. That testimony will include the following:

(1) The purpose of the DSCSA and FDA regulations was to help prevent harmful drugs from entering the United States' drug supply chain, detect harmful drugs if they do enter the supply chain, and enable rapid response to remove harmful drugs from the supply chain, all to protect patients;

(2) Identification by wholesale distributors of illegitimate and suspect products;

(3) Circumstances under which wholesale distributors of prescription drugs, such as Safe Chain, were required to quarantine and investigate suspect products;

(4) DSCSA records-keeping requirements for wholesale distributors of prescription drugs; and

(5) Notification procedures (including filing FDA Form 3911s) and requirements for when wholesale distributors of prescription drugs, such as Safe Chain, were required to notify FDA of illegitimate products (as defined in 21 U.S.C. § 360eee(8)) in their possession or control, for reasons such as that the product was: (a) counterfeit, diverted, or stolen; (b) intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (c) the subject of a fraudulent transaction; and (d) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

The basis of Ms. Picard's testimony will be her training and experience working at the FDA since December 2008, including her role in FDA's Office of Drug Security, Integrity, and Response where she regularly reviewed and assessed FDA Form 3911s and reviewed and updated policies and procedures pertaining to FDA Form 3911s under the DSCSA, in an effort to minimize the public's exposure to diverted, misbranded, and adulterated drugs and worked to protect the integrity of the prescription drug supply chain in the United States. Ms. Picard's qualifications and additional training and experience are reflected in her resume, which has been provided to the defense by email along with a disclosure letter.

2. Susmitha Sunkara and Harpreet Dhanota (Gilead Sciences)

Susmitha Sunkara and Harpreet Dhanota are fact witnesses who have personal knowledge regarding the topics they are expected to testify about at trial, including the falsity of the T3s/pedigrees associated with Gilead drugs that Safe Chain received and distributed to pharmacies throughout the United States as well as their review of physical evidence Gilead seized from Safe Chain (*e.g.,* bottles of Gilead prescription drugs, counterfeit outserts, etc.). The scope of their potential testimony on these topics is described in greater detail in their declarations and deposition testimony from Gilead's civil lawsuit against Safe Chain and the Defendants, which was previously produced to the defense. In addition, Susmitha Sunkara and Harpreet Dhanota will testify about the indicia or red flags that Gilead prescription drugs were not acquired legitimately *(i.e.*, diverted) and/or were counterfeit during the conspiracy period, such as when:

1) A T3/pedigree reflected a transaction between Gilead and a company that was not one of its Authorized Distributors;

2) Gilead prescription drugs were offered and sold to wholesale distributors at discounts greater than 5% off the Wholesale Acquisition Cost ("WAC");

3) A T3/pedigree identified a long list of purchasers of Gilead product (more than simply Gilead, an Authorized Distributor, and a pharmacy);

4) A T3/pedigree identified two or more pharmacies in the transaction history;

5) A T3/pedigree identified an Authorized Distributor such as McKesson, Cardinal, or AmerisourceBergen selling Gilead product to another wholesaler (rather than directly to a pharmacy); and

6) A T3/pedigree identified a sale from a distributor located in Puerto Rico to a company located in the continental United States.

The basis of Sunkara and Dhanota's testimony will be their personal knowledge and review of seized evidence in this case, their training and experience working at Gilead in roles specific to the topics they will testify about, and their prior education and training. Their qualifications and additional training and experience are reflected in copies of their LinkedIn profiles, which have been provided to the defense by email, along with a disclosure letter.

3. <u>Christopher Trent (Johnson & Johnson)</u>

Christopher Trent is a fact witness who has personal knowledge regarding the topics he is expected to testify about at trial, including the falsity of T3s/pedigrees associated with Johnson & Johnson ("J&J")/Janssen prescription drugs that Safe Chain received and distributed to pharmacies throughout the United States. The scope of Trent's potential testimony on these topics is described in greater detail in his deposition testimony and declarations from the *Janssen v. Safe Chain* civil litigation, which were produced to the defense. In addition, Trent will testify about the indicia or red flags that J&J/Janssen prescription drugs were not acquired legitimately (i.e., diverted) and/or counterfeit during the conspiracy period, such as when:

(1) A T3/pedigree reflected a transaction between J&J/Janssen and a company that was not one of its Authorized Distributors;

(2) J&J/Janssen prescription drugs were offered and sold to wholesale distributors at discounts greater than 5% off the Wholesale Acquisition Cost ("WAC");

(3) A T3/pedigree identified a long list of purchasers of J&J/Janssen product;

(4) A T3/pedigree identified two or more pharmacies in the transaction history;

(5) A T3/pedigree identified an Authorized Distributor such as McKesson, Cardinal, or AmerisourceBergen selling J&J/Janssen product to another wholesaler (rather than directly to a pharmacy); and

(6) A T3/pedigree identified a sale from a distributor located in Puerto Rico to a company located in the continental United States.

The basis of Trent's testimony will be his personal knowledge and review of evidence in this case, his training and experience working at J&J/Janssen in roles specific to the topics he will testify about, and his prior education and training. Trent's qualifications and additional training and experience is reflected in his resume, which has been provided to the defense by email, along with a disclosure letter signed by the witness.

LEGAL STANDARD

The admission of "opinion" testimony through lay witnesses is governed by Federal Rule of Evidence 701. Non-expert (or lay) witnesses may only testify to opinions or inferences which are rationally based on the witnesses' perception, are helpful to the jury in understanding the witness's testimony or determining a fact in issue, and not based on specialized knowledge within the scope of Rule 702. *See* FED. R. EVID. 701. Subsection (c) was added in 2000, in an attempt to rein in the admission of expert testimony under the guise of lay opinion. FED. R. EVID. 701, Advisory Committee's note to 2000 amendment (noting that the amendment was aimed at "eliminat[ing] the risk that the reliability requirements set forth in Rule 702 will be evaded through the simple expedient of proffering an expert in lay witness clothing.").

The law in the 11th Circuit applying Rule 701 makes clear that "the opinions of lay witnesses may be introduced when those opinions are based on the firsthand knowledge or observation of the witness and are helpful in understanding his testimony or in the determination

of an issue of fact." *United States v. Smith*, 550 F.2d 277, 281 (5th Cir. 1977).[1] The determination of whether lay opinion testimony is admissible is based upon the nature of the testimony itself, and not whether the witness could be qualified as an expert. *United States v. LeCroy*, 441 F.3d 914, 927 (11th Cir. 2006). Moreover, this Circuit has repeatedly held that "Rule 701 does not prohibit lay witnesses from testifying based on particularized knowledge gained from their own personal experiences . . [or] based on 'particularized knowledge garnered from years of experience in the field'[.]" *United States v. Hill*, 643 F.3d 807, 841 (11th Cir. 2011) (quoting *Tampa Bay Shipbuilding & Repair Co*., 320 F.3d 1213, 1223 (11th Cir. 2003)); s*ee also United States v. Toll*, 804 F.3d 1344, 1355 (11th Cir. 2015) (lay witness testimony is admissible when "based on particularized knowledge gained from [witnesses'] own personal experience"). And lay witnesses are further permitted to offer opinions on an "ultimate issue to be decided by the trier of fact." FED. R. EVID. 704. *See e.g. Smith*, 550 F.2d at 281 (witnesses' opinion that defendant knew and understood the CETA regulations at issue in the case was a "critical issue to be determined at trial" and properly admitted pursuant to Rule 704).

While it is the Government's position that none of the testimony offered by these witnesses constitutes expert testimony within the scope of Rule 702 and the case law applying it, it is filing this notice out an abundance of caution in the event the Court finds that any aspect of these witnesses' testimony constitutes expert testimony. As mentioned above, the Government has also timely provided the defense with disclosure letters as of the date of this filing, which are attached as exhibits to this filing.

[1] While not directly analogous here, health care fraud cases tried in this Circuit and elsewhere have routinely admitted lay witness testimony about their observations. For example, courts have admitted testimony of therapists and social workers regarding patients they treated and the clinics where they worked, as well as lay opinion testimony consistent with Federal Rule of Evidence 701. *See, e.g., United States v. Moran*, 778 F.3d 942, 966-67 (11th Cir. 2015).

Dated: July 21, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Alexander Thor Pogozelski, hereby certify that on July 21, 2025, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF.

/s/ Alexander Thor Pogozelski
Alexander Thor Pogozelski